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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/890,562 | 10/09/2001 | Toshikazu Yoshikawa | 4296-145-US | 4594 |

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EXAMINER

FONDA, KATHLEEN KAHLER

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1623

DATE MAILED: 12/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/890,562 | YOSHIKAWA ET AL. |
| | Examiner | Art Unit |
| | Kathleen Kahler Fonda, Ph.D. | 1623 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10-0-01 (prel amdt) and 11-30-01 (IDS).

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-10 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claim 1 is objected to as informal because of the parenthetical clause. For the sake of clarity, Applicant is requested to remove the parentheses around the "wherein" clause.

Applicant is advised that should claim 1 be found allowable, claim 3 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 3 reads on the same agent as claim 1, regardless of the intended use.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating arteriosclerosis or slowing its progression, does not

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reasonably provide enablement for preventing or curing arteriosclerosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. A person skilled in the art would have been faced with an undue burden of experimentation in order to practice the entire scope of the invention as claimed.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1986). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The instant invention is in the pharmaceutical field. The Examiner recognizes that those of skill in this art often possess advanced degrees in medicine and/or related sciences, and generally have significant clinical or laboratory experience. Thus the level of skill of the artisan in this field is high. However, despite this high skill level, the pharmaceutical arts are generally recognized as unpredictable,

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and a very large amount of experimentation is needed in order to develop pharmaceutical agents and appropriate protocols for their administration to patients.

The Examples in the specification provide significant guidance as to how the invention may be used to treat arteriosclerosis or slow its progression. However, these teachings do not enable the entire scope of the invention as claimed because "preventing" reads on keeping arteriosclerosis from happening at all, regardless of circumstances which might promote it, and "curing" reads on reversing pre-existing disease. Applicant has not taught how to accomplish either of these goals, either by working example or otherwise. The state of the art is that arteriosclerosis often develops over the course of a lifetime and may be affected by genetic predisposition, and that complete reversal is unknown. Therefore, mere allegations that prevention or cure can be accomplished by administering chromanol glucosides would not have been sufficient to enable one skilled in the art at the time of the invention to practice these aspects of the invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Each of claims 1 and 5 lacks positive antecedent basis for "the hydrogen atom of the hydroxyl group in the saccharide residue" because each saccharide residue has more than one hydroxyl group. Thus the claims are indefinite.

Claim 8 lacks antecedent basis for the "method" of claim 1 because claim 1 recites an "agent." Applicant is advised that for all purposes other than this indefiniteness rejection, claim 8 is being examined as if it depended from method claim 5.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by MURASE et al. (A1). MURASE teaches chromanol glycoside compounds as required by claim 1 in the abstract, and a compound of claim 2 in Example 1. The compound of claim 2 is shown as an aqueous preparation in Example 11, thus meeting the limitations of claim 4. Thus the claims are anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in

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order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over MURASE et al. (A1) in view of CYNSHI et al. (B3).

Applicant claims a method for "preventing and curing arteriosclerosis" by administering a chromanol glucoside. This rejection is made based on the assumption that "preventing and curing arteriosclerosis" might possibly have been intended to encompass treating arteriosclerosis or slowing its progression.

MURASE teaches as set forth above. MURASE also teaches that formation of lipid peroxides is known to have a bearing on diseases including arteriosclerosis (see column 1, lines 14-23), and that the chromanol glucosides taught therein are antioxidants (see Examples 9 and 10 and the corresponding Figures). MURASE does not specifically state that the chromanol glucosides taught therein can be used to treat arteriosclerosis.

CYNSHI teaches that antioxidants are known in the art to be useful as antiatherogenic agents; see the abstract and the first two paragraphs on page 10123.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to use a chromanol

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glucoside as taught by MURASE for treating arteriosclerosis or slowing its progression. An ordinarily skilled worker would have been motivated to do so, with a reasonable expectation of success, because MURASE had taught that the compounds were antioxidants, and both MURASE and CYNSHI had suggested that antioxidants could be used to treat arteriosclerosis or slow its progression.

No claim is allowed.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see <http://www.uspto.gov/ebc/index.html> for more information. Also, <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm> may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30 a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.



Kathleen Kahler Fonda, Ph.D., J.D.
Primary Examiner
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